REMARKS

I. Introduction

The undersigned thanks Examiner Pepitone for his review and consideration of the present Application. In response to the Final Office Action mailed February 3, 2009, the undersigned submits the present amendment and remarks ("Response"). Upon entry of the Response, claims 1-8, 11-32, 35-53, and 56-58 are pending in the application. The Response amends claim 1. Applicant requests entry of the amendment as the amendment does not add new subject matter not previously searched. No new matter has been added by the Response.

The Response is believed to overcome all of the prior Office Action rejections, and allowance of the pending claims is respectfully requested.

II. Rejections based on 35 U.S.C. § 102

The Final Office Action rejected claims 1-4, 11-12, 17-21, and 25-29 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,527,341 to Gogolewski *et al.* (hereinafter "Gogolewski"). The Final Office Action also rejected claims 1-8, 11-12, 17-32, and 35-37 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,303,697 to Yuan *et al.* (hereinafter "Yuan"). The undersigned respectfully traverses these rejections and requests that they be withdrawn.

For a reference to anticipate a claim under § 102, it must describe each and every element set forth in the claim. MPEP § 2131. As described in detail below, neither Gogolewski nor Yuan describes, either expressly or inherently, each and every element set forth in independent claim 1. Accordingly, neither Gogolewski nor Yuan discloses each and

every element of claims 2-8, 11-12, 17-32, and 35-37 which depend from and further limit claim 1.

Rejections based on Gogolewski

Gogolewski does not disclose oriented fibers as recited by amended claim 1 and does not disclose a process capable of producing an oriented fiber. In contrast to fibers, Gogolewski discloses devices comprising membranes for the attachment of tendons. Furthermore, Gogolewski discloses producing the devices by injection molding, cutting the device out of an extruded ribbon using a stamp, and solution casting and subsequent compression molding. None of the disclosed processes produce oriented fibers or filaments.

Accordingly, Applicant respectfully submits that Gogolewski does not disclose oriented fibers and, therefore, does not disclose each and every element of amended claim 1. Applicant, therefore, respectfully submits that claim 1 is patentable over Gogolewski. As claims 2-4, 11-12, 17-21, and 25-29 depend from and further limit claim 1 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable over Gogolewski for at least the same reasons that claim 1 is patentable.

Based on the foregoing, Applicant respectfully submits that claims 1-4, 11-12, 17-21, and 25-29 are in condition for allowance and respectfully requests that the present rejection be withdrawn.

Rejections based on Yuan

Yuan does not disclose a glycolic acid co-polymer having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa as recited in claim 1. It is the Examiner's

position that the polymers disclosed by Yuan inherently possess the mechanical properties recited in claim 1.

A rejection based on inherency is appropriate when a claim recites a function, property, or characteristic of a composition and the prior art discloses the ***same composition***, but ***does not explicitly disclose the function, property, or characteristic***. MPEP 2112 (III). Furthermore, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP § 2112 (IV) (emphasis in original) (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112 (IV) (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990) (emphasis in original)).

Applicant respectfully submits that the rejection of independent claim 1 as inherently anticipated by Yuan is improper because Yuan ***does*** explicitly disclose the mechanical properties of the polymers taught by that reference (maximum tensile strength of 143.9 ksi (992 MPa) and maximum tensile modulus of 2100 ksi (14.5 GPa)), and those mechanical properties are ***lower*** than the mechanical properties recited in claim 1 (tensile strength of at least 1100 MPa and tensile modulus of at least 20 GPa).

The Examiner argues that the difference in the tensile strength and modulus values recited in claim 1 and the values disclosed by Yuan could be attributed to variation in testing protocol and technique. The claimed polymers and the polymers disclosed in Yuan are not identical (as explained in detail below), so the different values cannot be solely attributed to

variation in testing protocol and technique. Additionally, Applicant respectfully submits that, as stated above, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."

It is well known in the art that a polymer's mechanical properties are not derived solely from it's chemical composition. One specific well known example is the difference in the mechanical properties of low density polyethylene (LDPE) and high density polyethylene (HDPE). These polymers are both polymerized from ethylene monomers, but they have vastly different mechanical properties. For example, HDPE has higher tensile strength, while LDPE has greater ductility. Additionally, it is well known in the art that processing affects a polymer's physical properties, including degree of orientation and degree of crystallization. These physical properties affect the polymer's mechanical properties, such as strength and flexibility. Thus, two polymers that have the same chemical composition can have different mechanical properties. That is, the mechanical properties of one polymer are not ***necessarily*** present in another polymer even if the polymers have the same chemical composition.

In this case, it is known, and the examiner has acknowledged, that the claimed polymers and the polymers disclosed in Yuan are subjected to different processing (i.e. Yuan does not include a quenching step). Because variations in processing can lead to variations in physical properties, the polymer compositions are not identical. These variations in physical properties can lead to variations in the mechanical properties of the polymers. Thus, the polymers of Yuan do not ***necessarily*** have the same mechanical properties as the claimed polymers.

In view of the foregoing, the Examiner has failed to provide extrinsic evidence showing that the polymers disclosed in Yuan and the claimed polymers are identical. Furthermore, Yuan affirmatively states that the polymers disclosed therein have mechanical properties outside the range recited in claim 1. As a result, the Examiner's has failed to satisfy his burden of showing a reasonable basis in fact and/or technical reasoning that the allegedly inherent characteristic ***necessarily*** flows from the teachings of the prior art.

Additionally, Applicant respectfully submits that the application contains adequate disclosure regarding how to obtain the claimed properties and effects with only the claimed ingredients. The application describes, in detail, the process for obtaining the claimed properties. (Specification, ¶¶ [0014]-[0020].) The application also provides specific examples whereby fibers with the claimed properties were formed. (Specification, ¶¶ [0040]-[0041].)

Applicant respectfully submits that the properties recited in claim 1 are not inherent in the polymers disclosed in Yuan. As a result, Yuan does not anticipate that claim 1. As claims 2-8, 11-12, 17-32, and 35-37 depend from and further limit claim 1 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable over Yuan for at least the same reasons that independent claim 1 is patentable.

Based on the foregoing, Applicant respectfully submits that claims 1-8, 11-12, 17-32, and 35-37 are in condition for allowance and respectfully requests that the present rejection be withdrawn.

III. Rejections based on 35 U.S.C. § 103

The Final Office Action rejected claims 13-16, 38-53, and 56-58 under 35 U.S.C. § 103(a) as being unpatentable over Yuan in view of U.S. Patent 4,700,704 to Jamiolkowski *et al.* (hereinafter "Jamiolkowski"). The Final Office Action also rejected claim 15 under 35 U.S.C. 103(a) as being unpatentable over Yuan in view of Jamiolkowski and further in view of Okuzaki *et al.* (*Journal of Polymer Science: Part B: Polymer Physics* **1999**, *37*, 991-996) (hereinafter "Okuzaki"). Applicant respectfully traverses these rejections and requests reconsideration in light of the foregoing amendments and the following remarks.

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex*, Federal Register, Vol. 72, No. 195, p. 57527 (October 10, 2007) explain what is required where an obviousness rejection is made:

> As reiterated by the Supreme Court in *KSR,* the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deer Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:
>
> (1) Determining the scope and content of the prior art;
>
> (2) Ascertaining the differences between the claimed invention and the prior art; and
>
> (3) Resolving the level of ordinary skill in the pertinent art.
>
> Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .
>
> Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquires. . . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . .

> Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C 103.

The Final Office Action **does not comply with these requirements**.

Applicant respectfully submits that the Examiner has failed to make and articulate findings of fact that support an obviousness rejection under 35 U.S.C. § 103. For the reasons explained in detail below (A) the cited references, singly or in combination, do not teach or suggest each and every element of the claimed invention; and (B) one of skill in the art would lack the motivation to combine the cited references to arrive at the claimed invention.

A. The cited references, singly or in combination, do not teach or suggest each and every element of the claimed invention.

The Examiner has failed to present a *prima facie* case of obviousness at least because the references do not teach or suggest all of the limitations of claim 13.

Claim 13 incorporates claim 1, which recites a glycolic acid co-polymer having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa. As discussed above, Yuan discloses polymers having a maximum tensile strength of 992 MPa and a maximum modulus of 14.5 GPa. Thus, Yuan does not teach or suggest a copolymer having the properties recited in claim 13. Jamiolkowski discloses polymer compositions that have a maximum tensile strength of 786 MPa and a maximum modulus of 7.8 GPa. Thus, Jamiolkowski also does not teach or suggest a copolymer having the properties recited in claim 13. As a result, neither Yuan nor Jamiolkowski teaches or suggests a glycolic acid copolymer having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa.

Accordingly, Applicant respectfully submits that Yuan and Jamiolkowski, singly or in combination, do not teach or suggest each and every element of claim 13. As a result, Applicant respectfully submits that claim 13 is patentable over Yuan in view of Jamiolkowski. As claims 14-16, 38-53, and 56-58 depend from and further limit claim 13 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable for at least the same reasons that independent claim 13 is patentable.

With respect to the rejection of claim 15, Okuzaki discloses polymers having a maximum tensile strength of 275 MPa and a maximum modulus of 9.1 GPa. Thus, Okuzaki also does not disclose a glycolic acid copolymer having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa, and Okuzaki does not cure the deficiency of Yuan and Jamiolkowski. Accordingly, Applicant respectfully submits that claim 15 is patentable over Yuan in view of Jamiolkowski and further in view of Okuzaki.

The Examiner has thus failed to present a *prima facie* case of obviousness at least because the cited references do not teach or suggest glycolic acid co-polymer compositions having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa. Accordingly, Applicant respectfully submits that claims 13-16, 38-53, and 56-58 are in condition for allowance and respectfully requests that the present rejection be withdrawn.

B. One of skill in the art would lack the motivation to combine the cited references to achieve the compositions of the present invention.

Claim 13 incorporates the composition of claim 1 and further recites a process for manufacturing the composition which includes forming fibers, quenching the fibers, and drawing the fibers. Yuan teaches forming fibers by known methods such as extrusion and

solution spinning and teaches that those fibers may be drawn. As recognized by the Examiner in the Office Action, Yuan does not teach or suggest quenching the fibers after they are formed and before they are drawn. (Office Action mailed February 3, 2009, page 5.)

Jamiolkowski discloses filaments having "desirable straight and knot tensile strength . . . and low modulus." These filaments are made by a process that includes melt spinning, taking up the extrudate in ice water, winding the extrudate onto a spool, storing the wound extrudate under reduced pressure, drawing the filaments, and heat setting the drawn filaments. Filaments produced by the foregoing process of Jamiolkowski have a maximum tensile strength of 786 MPa and a maximum tensile modulus of 7.8 GPa. A maximum tensile strength of 786 MPa and a maximum tensile modulus of 7.8 GPa is significantly less than those of the polymer compositions of the present application (1100 MPa and 20 GPa) and significantly less than those of the polymer compositions of Yuan (992 MPa and 14.5 GPa).

In accordance with the recited goal of providing polymer compositions of lower tensile strength and tensile modulus, Jamiolkowski's desirable mechanical properties are incongruent with the mechanical properties achieved by polymer compositions of the present invention. Accordingly, one of skill in the art desiring to ***increase*** the strength and modulus of the polymers disclosed in Yuan to the strength and modulus recited in the current claims would not look to a reference (i.e., Jamiolkowksi) that teaches a method that results in the exact opposite result — polymers having a lower tensile strength and modulus.

Furthermore, while claim 13 recites forming fibers, quenching, and drawing, the combination of Yuan and Jamiolkowski provides melt spinning, quenching, winding, storing

under reduced pressure, drawing, and heat setting. The Examiner has not provided reasoning to support the obviousness of choosing only the quenching step — which is one of several additional steps disclosed by Jamiolkowski — to combine with the process of Yuan.

Applicant respectfully submits that one of skill in the art would not be motivated to achieve compositions having the strength and modulus recited in claim 13 by modifying Yuan to add the quenching step — and only the quenching step — of Jamiolkowski. Accordingly, Applicant respectfully submits that the combination of Yuan and Jamiolkowski is based on hindsight reconstruction of Applicant's own invention. As a result, Applicant respectfully submits that claim 13 is patentable over Yuan in view of Jamiolkowski. As claims 14-16, 38-53, and 56-58 depend from and further limit claim 13 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable for at least the same reasons that independent claim 13 is patentable and may be patentable for additional reasons.

The Examiner has thus failed to present a *prima facie* case of obviousness at least because one of skill in the art would lack the motivation to combine the cited references. Accordingly, Applicant respectfully submits that claims 13-16, 38-53, and 56-58 are in condition for allowance and respectfully requests that the present rejection be withdrawn

IV. Rejection of Claims based on Double Patenting

Claims 1-8, 11-32, 35-53, and 56-58 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 7,455,674.

Applicants respectfully request that this issue be deferred until the claims in the present application are in condition for allowance. At such time Applicants will file an appropriate terminal disclaimer if necessary.

CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed February 3, 2009. Applicant respectfully asserts that the claims are in condition for allowance and respectfully requests that the application be passed to issuance. Any fees due at this time may be charged to Deposit Account number 11-0855. If the Examiner believes that any informalities remain in the case that can be resolved by telephone interview, a telephone call to the undersigned at 404-815-6040 is respectfully solicited.

Respectfully submitted,

Jennifer L. Blackburn, Ph.D.
Registration No. 53,994

KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia 30309-4530
(404) 815-6040